REMARKS

This Amendment is submitted in reply to the Non-Final Office Action mailed on July 31, 2008. No fee is due in connection with this Amendment. The Commissioner is hereby authorized to charge any fees which may be required or credit any overpayment to Deposit Account No. 02-1818. If such a withdrawal is made, please indicate the Attorney Docket No. 112701-911 on the account statement.

Claims 12-30 are pending. Claims 1-11 were previously canceled without prejudice or disclaimer. Claim 27 was previously withdrawn. In the Office Action, Claims 18, 21 and 27-29 are rejected under 35 U.S.C. §101. Claims 12-26 and 28-30 are rejected under 35 U.S.C. §112, first paragraph. Claims 18, 21, 24 and 27-29 are rejected under 35 U.S.C. §112, second paragraph. Claims 12-22, 24-26 and 28-30 are rejected under 35 U.S.C. §102. Claims 19-22, 25-26 and 28-30 are rejected under 35 U.S.C. §103. In response, Claims 12-26 and 28-30 have been amended. The amendments do not add new matter. In view of the amendments and/or for the reasons set forth below, Applicants respectfully submit that the rejections should be withdrawn.

Applicants note that, for the purposes of examination of the pending claims, the Patent Office has renumbered misnumbered Claims 26-29, which were intended to be numbered 27-30 to avoid duplicative numbering of Claim 26. As such, Applicants have now also renumbered misnumbered Claims 26-29 to Claims 27-30 for clarity purposes.

Applicants also confirm the provisional election by Gary Lobel on July 22, 2008 to prosecute the invention of group I of the Restriction Requirement, which includes Claims 12-26 and 28-30. As such, Claim 27 (Group II) is withdrawn from further consideration by the Patent Office.

In the Office Action, Claims 18, 21 and 27-29 are rejected under 35 U.S.C. § 101 because the Patent Office alleges that the claims recite a use without setting forth any steps involved in the process. See, Office Action, page 4, lines 6-9. In response, Claims 18 and 21 have been amended to recite, in part, methods for inhibiting pathogen adhesion or for treating pathogen-associated enteric disorders comprising administering to a mammal certain compounds or combinations of compounds. Similarly, Claims 28-30 have been amended to recite, in part, methods for the manufacture of a nutritional or pharmaceutical composition for the inhibition of

pathogenic bacteria adhesion to mammalian cells, or for reducing or inhibiting the invasion and infection of mammalian cells by pathogenic bacteria, the method comprising adding to a nutritional or pharmaceutical composition a compound or combinations of compounds. The amendments do not add new matter. The amendments are supported in the specification at, for example, page 1, line 20-page 3, line 8. As amended, Applicants respectfully submit that Claims 18, 21 and 28-30 now positively recite process steps and, as such, fully comply with the requirements of 35 U.S.C. §101.

Accordingly, Applicants respectfully request that the rejection of Claims 18, 21 and 27-29 under 35 U.S.C. §101 be withdrawn.

Similarly, Claims 18, 21 and 27-29 are rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for reciting a use without any active, positive steps delimiting how the use is actually practiced. See, Office Action, page 4, lines 16-20. In response, and as discussed above, Claims 18 and 21 have been amended to recite, in part, methods for inhibiting pathogen adhesion or for treating pathogen-associated enteric disorders comprising administering to a mammal certain compounds or combinations of compounds. Similarly, Claims 28-30 have been amended to recite, in part, methods for the manufacture of a nutritional or pharmaceutical composition for the inhibition of pathogenic bacteria adhesion to mammalian cells, or for reducing or inhibiting the invasion and infection of mammalian cells by pathogenic bacteria, the method comprising adding to a nutritional or pharmaceutical composition a compound or combinations of compounds. The amendments do not add new matter. The amendments are supported in the specification at, for example, page 1, line 20-page 3, line 8. As amended, Applicants respectfully submit that Claims 18, 21 and 28-30 now positively recite method steps and, as such, fully comply with the requirements of 35 U.S.C. §112, second paragraph.

In the Office Action, Claim 24 is also rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. See, Office Action, page 4, line 21-page 5, line 1. Specifically, the Patent Office alleges that Claim 24 recites the broad range manno-oligosaccharides and/or methyl manno-oligosaccharides, and the Claim also recites the limitation "in particular chosen from alpha 1,2-mannobioses, alpha 1,3-mannobioses, alpha 1, 6-

mannobioses, or methyl alpha manno-oligosaccharides, which is the narrower statement of the range/limitation." See, Office Action, page 5, lines 12-16.

In response, Applicants have amended Claim 24 to recite a nutritional or pharmaceutical composition comprising at least one compound selected from the group consisting of alpha 1-2 mannobioses, alpha 1-3 mannobioses, alpha 1-6 mannobioses, methyl alpha manno-oligosaccharides, and combinations thereof. The amendment does not add new matter. The amendment is supported in the specification at, for example, page 2, lines 7-11. As such, Applicants respectfully submit that Claim 24 does not claim "a broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation" as alleged by the Patent Office. Accordingly, Applicants respectfully submit that Claim 24 fully complies with the requirements of 35 U.S.C. §112, second paragraph.

Based on at least these noted reasons, Applicants believe that Claims 18, 21, 24 and 27-29 fully comply with 35 U.S.C. §112, second paragraph.

Accordingly, Applicants respectfully request that the rejection of Claims 18, 21, 24 and 27-29 under 35 U.S.C. §112, second paragraph be withdrawn.

In the Office Action, Claims 12-23 and 28-30 are rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the enablement requirement. The Patent Office asserts that the specification does not enable one to practice the claimed methods of "preventing" the invasion and infection of mammalian cells by pathogen and that the specification does not reasonably provide enablement for the "prevention" of same. In response, Applicants have amended Claims 12, 16, 18-19 and 28-29 to delete the words "preventing" or "prevention" from the claims. According, Applicants respectfully submit that the deletion of the words "preventing" and "prevention" renders moot the rejections under 35 U.S.C. §112, first paragraph.

In the Office Action, Claims 12-26 and 28-30 are also rejected under 35 U.S.C. §112, first paragraph because the Patent Office alleges that, while the specification is enabling for compositions and methods for treating enteric bacterial disorder and infections, the specification does not reasonably provide enablement for treating all pathogens such as viruses and protozoa. See, Office Action, page 11, lines 1-4. The Patent Office further alleges that bacteria, viruses and protozoa are three families of pathogens that are distinct and unrelated such that there is no expectation whatsoever that a therapy that targets one class of pathogen will have any activity

against another. See, Office Action, page 12, lines 13-18. In response, Applicants have amended Claims 12, 16-19 and 28-29 to recite, in part compositions for the inhibition of pathogenic bacteria adhesion to mammalian cells, or for reducing or inhibiting the invasion and infection of mammalian cells by pathogenic bacteria. The amendments do not add new matter. The amendments are supported in the specification at, for example, page 2, line 31-page 3, line 2; page 7, line 5-page 8, line 7. As amended, Applicants respectfully submit that the claims are fully enabled by the specification.

Based on at least these noted reasons, Applicants believe that Claims 12-26 and 28-30 fully comply with 35 U.S.C. §112, first paragraph.

Accordingly, Applicants respectfully request that the rejection of Claims 12-26 and 28-30 under 35 U.S.C. §112, first paragraph, be withdrawn.

In the Office Action, Claims 12-14, 16-22, 25-26 and 28-30 are rejected under 35 U.S.C §102(b) as being anticipated by U.S. Patent No. 5,683,991 to Guggenbichler et al. ("*Guggenbichler*"). Specifically, the Patent Office alleges that *Guggenbichler* discloses oligogalacturonides, pectic oligosaccharides and pectin. See, Office Action, page 15, lines 3-11. However, Applicants respectfully submit that *Guggenbichler* is deficient with respect to the present claims.

Currently amended independent Claims 12, 16, 18-19, 25 and 28-29 recite, in part, compounds selected from the group consisting of manno-oligosaccharides, caseinoglycomacropeptides (COMP), methyl manno-oligosaccharides, chito-oligosaccharides, isomalto-oligosaccharides, partially hydrolysed guar gum, gentio-oligosaccharides, arabino-oligosaccharides, lactose, lactosucrose, long-chain isomalto-oligosaccharides, and combinations thereof. Applicants have surprisingly found that certain compounds including, but not limited to those disclosed above, survive passage through the gastrointestinal tract and inhibit the adhesion of specific pathogens to the colonic epithelium without adversely affecting the colonic microflora or adhesion of probiotic organisms. See, specification, page 1, lines 15-18. In contrast, however, Applicants respectfully submit that *Guggenbichler* fails to disclose each and every element of the present claims.

For example, *Guggenbichler* fails to disclose or suggest any of the presently claimed compounds disclosed in currently amended independent Claims 12, 16, 18-19, 25 and 28-29.

Specifically, *Guggenbichler* fails to disclose or suggest compounds selected from the group consisting of manno-oligosaccharides, caseinoglycomacropeptides (COMP), methyl manno-oligosaccharides, chito-oligosaccharides, isomalto-oligosaccharides, partially hydrolysed guar gum, gentio-oligosaccharides, arabino-oligosaccharides, lactose, lactosucrose, long-chain isomalto-oligosaccharides, and combinations thereof as required, at least in part, by independent Claims 12, 16, 18-19, 25 and 28-29. Instead, *Guggenbichler* is entirely directed toward the administration of carrot soup in the classical preparation according to MORO to a mammal. The carrot soup contains pectins, which are essentially chains of 1,4-α-galacturonides, which are said to block the attachment of germs to mammalian cells. See, *Guggenbichler,* col. 1, lines 12-61. However, since *Guggenbichler* fails to disclose or suggest the presently claimed compounds, *Guggenbichler* fails to anticipate the present claims.

In the Office Action, Claims 12-13, 16-21 and 28-30 are rejected under 35 U.S.C §102(b) as being anticipated by WO 01/65949 to Baillon et al. ("*Baillon*"). Specifically, the Patent Office alleges that *Baillon* discloses galactooligosaccharides and lactosucrose. See, Office Action, page 15, lines 3-11. However, Applicants respectfully submit that *Baillon* is deficient with respect to the present claims.

As discussed above, currently amended independent Claims 12, 16, 18-19 and 28-29 recite, in part, compounds selected from the group consisting of manno-oligosaccharides, caseinoglycomacropeptides (COMP), methyl manno-oligosaccharides, chito-oligosaccharides, isomalto-oligosaccharides, partially hydrolysed guar gum, gentio-oligosaccharides, arabino-oligosaccharides, lactose, lactosucrose, long-chain isomalto-oligosaccharides, and combinations thereof. In contrast, however, Applicants respectfully submit that *Baillon* fails to disclose each and every element of the present claims.

For example, *Baillon* fails to disclose or suggest any of the presently claimed compounds disclosed in currently amended independent Claims 12, 16, 18-19 and 28-29. Specifically, *Baillon* fails to disclose or suggest compounds selected from the group consisting of manno-oligosaccharides, caseinoglycomacropeptides (COMP), methyl manno-oligosaccharides, chito-oligosaccharides, isomalto-oligosaccharides, partially hydrolysed guar gum, gentio-oligosaccharides, arabino-oligosaccharides, lactose, lactosucrose, long-chain isomalto-oligosaccharides, and combinations thereof as required, at least in part, by independent Claims

12, 16, 18-19 and 28-29. Instead, *Baillon* is entirely directed toward the use of a non-digestible carbohydrate in the manufacture of a composition for treating or preventing pathogenic bacteria in the large intestine of a pet animal. See, *Baillon,* Abstract. However, since *Baillon* fails to disclose or suggest the presently claimed compounds, *Baillon* fails to anticipate the present claims.

In the Office Action, Claims 12-14 and 16-18 are rejected under 35 U.S.C §102(b) as being anticipated by WO 98/42311 to Akiyama et al. ("*Akiyama*"). Specifically, the Patent Office alleges that *Akiyama* discloses curdlan as an active ingredient. See, Office Action, page 16, lines 6-9. However, Applicants respectfully submit that *Akiyama* is deficient with respect to the present claims.

As discussed above, currently amended independent Claims 12, 16 and 18 recite, in part, compounds selected from the group consisting of manno-oligosaccharides, caseinoglycomacropeptides (COMP), methyl manno-oligosaccharides, chito-oligosaccharides, isomalto-oligosaccharides, partially hydrolysed guar gum, gentio-oligosaccharides, arabino-oligosaccharides, lactose, lactosucrose, long-chain isomalto-oligosaccharides, and combinations thereof. In contrast, however, Applicants respectfully submit that *Akiyama* fails to disclose each and every element of the present claims.

For example, *Akiyama* fails to disclose or suggest any of the presently claimed compounds disclosed in currently amended independent Claims 12, 16 and 18. Specifically, *Akiyama* fails to disclose or suggest compounds selected from the group consisting of manno-oligosaccharides, caseinoglycomacropeptides (COMP), methyl manno-oligosaccharides, chito-oligosaccharides, isomalto-oligosaccharides, partially hydrolysed guar gum, gentio-oligosaccharides, arabino-oligosaccharides, lactose, lactosucrose, long-chain isomalto-oligosaccharides, and combinations thereof as required, at least in part, by independent Claims 12, 16 and 18. Instead, *Akiyama* is entirely directed toward compositions having an active ingredient that swells, has favorable safety characteristics and an enhanced adhesion to the mucosa. See, *Akiyama,* Abstract. However, since *Akiyama* fails to disclose or suggest the presently claimed compounds, *Akiyama* fails to anticipate the present claims.

In the Office Action, Claims 12-14 and 16-18 are rejected under 35 U.S.C §102(b) as being anticipated by "The Sialylated Fraction of Milk Oligosaccharides Is Partially Responsible

for Binding to Enterotoxigenic and Uropathogenic Escherichia coli Human Strains" to Martin-Sosa et al. ("*Martin-Sosa*"). Specifically, the Patent Office alleges that *Martin-Sosa* discloses nutritional or pharmaceutical compositions containing oligosaccharides and sialylated oligosaccharides. See, Office Action, page 16, lines 12-18. However, Applicants respectfully submit that *Martin-Sosa* is deficient with respect to the present claims.

As discussed above, currently amended independent Claims 12, 16 and 18 recite, in part, compounds selected from the group consisting of manno-oligosaccharides, caseinoglycomacropeptides (COMP), methyl manno-oligosaccharides, chito-oligosaccharides, isomalto-oligosaccharides, partially hydrolysed guar gum, gentio-oligosaccharides, arabino-oligosaccharides, lactose, lactosucrose, long-chain isomalto-oligosaccharides, and combinations thereof. In contrast, however, Applicants respectfully submit that *Martin-Sosa* fails to disclose each and every element of the present claims.

For example, *Martin-Sosa* fails to disclose or suggest any of the presently claimed compounds disclosed in currently amended independent Claims 12, 16 and 18. Specifically, *Martin-Sosa* fails to disclose or suggest compounds selected from the group consisting of manno-oligosaccharides, caseinoglycomacropeptides (COMP), methyl manno-oligosaccharides, chito-oligosaccharides, isomalto-oligosaccharides, partially hydrolysed guar gum, gentio-oligosaccharides, arabino-oligosaccharides, lactose, lactosucrose, long-chain isomalto-oligosaccharides, and combinations thereof as required, at least in part, by independent Claims 12, 16 and 18. Instead, *Martin-Sosa* is entirely directed toward experiments for determining any ability of human milk oligosaccharides to bind two human ETEC strains and to attempt to clarify to what extent any binding could be due to acidic fractions. See, *Martin-Sosa,* page 3067, col. 2. However, since *Martin-Sosa* fails to disclose or suggest the presently claimed compounds, *Martin-Sosa* fails to anticipate the present claims.

In the Office Action, Claims 12-17 and 24 are rejected under 35 U.S.C §102(b) as being anticipated by "Synthesis of α1-6-Mannooligosaccharides in *Mycobacterium smegmatis*" to Yokoyama et al. ("*Yokoyama*"). Specifically, the Patent Office alleges that *Yokoyama* discloses α1-6-Mannooligosaccharides and that the α1-6-Mannooligosaccharides are "reasonably considered to be a pharmaceutical or nutritional composition according to the instant claims as it could be administered to a subject to produce a therapeutic effect." See, Office Action, page 17,

lines 3-9. However, Applicants respectfully submit that *Yokoyama* is deficient with respect to the present claims.

Currently amended independent Claims 12, 16 and 24 recite, in part, nutritional or pharmaceutical compositions comprising compounds selected from the group consisting of manno-oligosaccharides, caseinoglycomacropeptides (COMP), methyl manno-oligosaccharides, chito-oligosaccharides, isomalto-oligosaccharides, partially hydrolysed guar gum, gentio-oligosaccharides, arabino-oligosaccharides, lactose, lactosucrose, long-chain isomalto-oligosaccharides, and combinations thereof. In contrast, however, Applicants respectfully submit that *Yokoyama* fails to disclose each and every element of the present claims.

For example, *Yokoyama* fails to disclose or suggest any of the presently claimed compounds disclosed in currently amended independent Claims 12, 16 and 24. Specifically, *Yokoyama* fails to disclose or suggest nutritional or pharmaceutical compositions comprising compounds as required, at least in part, by independent Claims 12, 16 and 24. In the specification, Applicants make readily apparent that the compounds of the present invention are not the same as the nutritional or pharmaceutical compositions that are presently claimed. For example, in the specification, Applicants state "[i]n one aspect of the invention, there is provided a medicament, nutritional or pharmaceutical formulation, for example [a] dietary supplement, comprising a compound of the invention." See, specification, page 8, lines 9-12. Applicants continue to discuss how the medicaments, nutritional or pharmaceutical compositions may include additional ingredients such as carriers, food additives, vitamins, minerals, trace elements, carbohydrates, fatty acids, proteins, etc. See, specification, page 8, lines 14-33; page 10, lines 19-24.

Accordingly, Applicants respectfully submit that the "nutritional or pharmaceutical compositions" of the present invention are not defined by Applicants to include solely the claimed "compounds" of the present invention. Instead, Applicants respectfully submit that the "nutritional or pharmaceutical compositions" of the present invention are intended to include other ingredients combined with the "compounds" to make nutritional or pharmaceutical compositions. Further, Applicants respectfully submit that the skilled artisan would immediately appreciate that the "nutritional or pharmaceutical compositions" of the presently claimed subject

matter, when read in view of the specification, would require ingredients in addition to the presently claimed "compounds."

In contrast, *Yokoyama* is entirely directed toward methods for the synthesis of α1-6-mannooligosaccharides and fails to disclose or suggest that the α1-6-mannooligosaccharides may be manufactured and used in a nutritional or pharmaceutical composition as required, in part, by the present claims. See, *Yokoyama,* page 3067, col. 2. Since *Yokoyama* fails to disclose or suggest the presently claimed nutritional or pharmaceutical compositions, *Yokoyama* fails to anticipate the present claims.

Further, anticipation is a factual determination that "requires the presence in a single prior art disclosure of each and every element of a claimed invention." *Lewmar Marine, Inc. v. Barient, Inc.*, 827 F.2d 744, 747 (Fed. Cir. 1987) (emphasis added). Federal Circuit decisions have repeatedly emphasized the notion that anticipation cannot be found where less than all elements of a claimed invention are set forth in a reference. See, *e.g.*, *Transclean Corp. v. Bridgewood Services, Inc.*, 290 F.3d 1364, 1370 (Fed. Cir. 2002). As such, a reference must clearly disclose each and every limitation of the claimed invention before anticipation may be found. Because the cited references fail to disclose each and every element of the present claims, the cited references fail to anticipate the present claims.

For at least these reasons, Applicants respectfully submit that *Guggenbichler*, *Baillon*, *Akiyama*, *Martin-Sosa* and *Yokoyama* all fail to anticipate the presently claimed subject matter.

Accordingly, Applicants respectfully submit that the anticipation rejections with respect to Claims 12-22, 24-26 and 28-30 be reconsidered and withdrawn.

In the Office Action, Claims 19-22, 25-26 and 28-30 are rejected under 35 U.S.C. § 103(a) as being unpatentable over *Martin-Sosa*. However, for at least the reasons discussed above with respect to *Martin-Sosa*, Applicants respectfully submit that *Martin-Sosa* fails to disclose or suggest every element of Claims 19-22, 25-26 and 28-30. Specifically, *Martin-Sosa* fails to disclose or suggest compounds selected from the group consisting of manno-oligosaccharides, caseinoglycomacropeptides (COMP), methyl manno-oligosaccharides, chito-oligosaccharides, isomalto-oligosaccharides, partially hydrolysed guar gum, gentio-oligosaccharides, arabino-oligosaccharides, lactose, lactosucrose, long-chain isomalto-oligosaccharides, and combinations thereof as required, at least in part, by independent Claims

19, 25 and 28-29. Instead, *Martin-Sosa* is entirely directed toward experiments for determining any ability of human milk oligosaccharides to bind two human ETEC strains and to attempt to clarify to what extent any binding could be due to acidic fractions. See, *Martin-Sosa,* page 3067, col. 2. For at least these reasons, Applicants respectfully submit that *Martin-Sosa* fails to render the presently claimed subject matter obvious.

Accordingly, Applicants respectfully submit that the obviousness rejections with respect to Claims 19-22, 25-26 and 28-30 be reconsidered and withdrawn.

For the foregoing reasons, Applicants respectfully request reconsideration of the above-identified patent application and earnestly solicit an early allowance of same. In the event there remains any impediment to allowance of the claims which could be clarified in a telephonic interview, the Examiner is respectfully requested to initiate such an interview with the undersigned.

Respectfully submitted,

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